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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Fred T. Lee JR.

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EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3769

NOTIFICATION DATE

DELIVERY MODE

04/02/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@boylefred.com

Office Action Summary	Application No. 10/796,239	Applicant(s) LEE ET AL.	
	Examiner david shay	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 18, 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 13, 16-22 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13, 16-22 and 28-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “the first and second electrode set each comprising 3 wires positionable at angularly offset radial points around the shaft configuration” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The instant response includes a Declaration (hereinafter the “Haemmerich Declaration”) by Dr. Deiter Haemmerich (hereinafter “Declarant”). The examiner will now evaluate the Haemmerich Declaration.

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In paragraphs 1-5 Declarant identifies himself, noting that he is one of the instant inventors, and enumerates his education, positions he has held, issued patents, and peer-reviewed articles which he has published. In paragraph 6, Declarant asserts he has reviewed the previous office action and the references applied therein, noting that the reference to Gough applied to the claims was printed with Rita Medical Systems, Inc. as the assignee. In paragraph 7, Declarant asserts that he has been requested to comment the examiner's assertion that it would have been obvious at the time of the invention to the artisan of ordinary skill to provide each shaft as an insulated metal tubular member in a coaxial configuration, and to provide an insulated portion, and to provide an insulated portion of the trocar between two sets of antennae. In paragraph 8, Declarant states that his understanding claim 28 depends from claim 16 and that he understands the limitations of claim 16. In paragraph 9, Declarant asserts that he understands the limitations of claim 28. In paragraph 10, Declarant asserts familiarity with Rita Medical equipment, as such equipment was part of the starting materials for construction of "our prototypes of our invention" and Declarant further notes that the Rita Medical equipment "could not be used...without significant modification". In paragraph 11, Declarant provides a sketch of a Rita Model 30 probe, as of the year 2000, noting that it "can be referred to as an electrode set". In paragraph 12, Declarant asserts that in "these probes" (presumably the Rita Model 30 probes) power is applied between at least one of the electrodes and a grounding pad. In paragraph 13, Declarant asserts that he was unaware of any "devices with multiple electrode sets" that were commercially available in the year 2000. Declarant further asserts that "these electrode sets were designed to be used one set at a time", but provides no evidentiary showing of this, such as an admonition in the product literature not to use more than one electrode set at a time. Continuing, Declarant

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asserts that in the year 2000 two electrode sets were used, and required the modification of insulating the an upper end of the shaft of the electrode set that protruded beyond the shaft of the other electrode set, and that power was applied between the two electrode sets (i.e. they were used in a bipolar mode), rather than using a grounding pad. In paragraph 14, Declarant asserts that there was nothing in the “product offerings” (presumably the literature accompanying the products ordered as raw materials) that suggested the use of two electrode sets together; that they be configured in a coaxial or side by side configuration; or that suggested using them in a bipolar mode. Declarant then states “In fact, all known radiofrequency ablation devices available in the year 2000 required a grounding pad, and there was no known commercial device of this type available for operating in a bipolar mode at that time” (presumably the term “known” is intended to be read “known by Declarant”). Declarant then concludes that that Declarant sees nothing to support the examiner’s finding referred to in paragraph 7 of the Haemmerich Declaration. In paragraph 15, Declarant asserts he has reviewed the Gough et al (’143) reference particularly column 7, lines 21-30 thereof, and opines that one of ordinary skill in the art would not conclude that this was referring to using two electrode sets. In paragraph 16, Declarant asserts he has reviewed the Gough et al (’143) reference particularly Figures and 8, and column 7, lines 21-34, and the remainder of the Gough et al (’143) reference, and opines that one of ordinary skill in the art at the time of the invention would not conclude that this was referring to coupling a power supply between two electrode sets to apply bipolar power. In paragraph 17, Declarant asserts that he has reviewed the passage at page 6, lines 14-22 of the previous office action. In paragraph 18, Declarant asserts that on review of Gough et al (’143) “all instances of reference number 14 refer to a trocar that is uninsulated” and when “an insulating sleeve is added, it always has the

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reference number 18” and Declarant further notes that this is consistent with the construction of the Rita Model 30 and opines that it “cannot be concluded that the upper end of trocar 14 in Fig. 4 is insulated from the description of the embodiment of Fig. 4” and asserts that “In fact, it would not be possible to obtain the heating zone shown as a dashed ellipse in Fig. 4 if trocar 14 was insulated” and also notes that there is no suggestion of insulation on the tip of the device in Figure 8. In paragraph 19, Declarant asserts that the subject matter of claim 29 would not be obvious for the same reasons and further because the side by side configuration allows improved positioning of the two electrode sets to better conform to tumor geometry. In paragraph 20, Declarant asserts that once “the Gough et al. ’143 patent is properly understood in view of the commercial embodiments of its assignee known in the period from 1995 to 2000, the findings in the Office action referred to above are not reasonable readings of what one of ordinary skill in the art would understand from the Gough et al. reference” and notes that Sawnsen adds nothing to change that conclusion.

Having evaluated the Haemmerich Declaration, the examiner will now analyze the statements therein. The examiner has no comment regarding the contents of paragraphs 1-10. Regarding Declarant’s assertions contained in paragraph 11, among them the “Rita Model 30, which can be referred to as an electrode set” the examiner notes that while this device can be referred to as “an electrode set” that for the purposes of patent examination, the language of the claims is given it’s broadest reasonable interpretation. The examiner further notes that, while the term “electrode set” appears many times in the originally filed disclosure, the term itself is never explicitly defined, thus it is given it’s broadest reasonable interpretation. The meaning of the term “electrode” is simply a conductive element that is used to transmit electrical energy to or

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from an electrical circuit from or to an external body, which could be another electrical circuit or could also be a living body. The term “set” means “a group of things of the same kind that belong together and are so used” (*American Heritage Dictionary*). The examiner has no comment regarding the contents of paragraphs 12. Regarding Declarant’s assertions contained in paragraph 13, the examiner respectfully notes that, as an initial matter, the perceived lack of availability of a product on the market by itself is of little moment with respect to the evaluation of the obviousness of a claimed invention in view of a publication. There could be any number of reasons not related to obviousness which are responsible for the absence of the product in the marketplace: the product could have been available, but unknown to Declarant, for example or the product may have been manufactured, but not have passed FDA approval, or the manufacturer may have developed and desired to produce the product, but not had sufficient capital to tool up for the production of the device. Thus standing alone, the absence of a commercial product which anticipates the claimed invention is given little weight with regard to the obviousness thereof in view of a patent, even a patent owned by an assignee which produces what Declarant feels is the closest available commercial product to that claimed either in the patent in question or the instant application. This is best illustrated by the fact that, according to the facts set forth in the Haemmerich Declaration, there is apparently no instruction or suggestion that the Rita Model 30 can be used in a bipolar mode, however, the Gough et al (’143) reference explicitly states this in a manner so clear, that even Declarant cannot dispute it: “Multiple antenna device **12** can be operated in the bipolar mode between the two antennas **16** or between the antenna and the trocar **14**.” (see Gough et al (’143), column 8, lines 9-11), bolding in original). As can readily be seen from the foregoing, the state of the commercial market is

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completely irrelevant to a rejection based on a U. S. Patent, when that Patent explicitly provides a teaching of the claimed invention. The examiner will also respectfully note here, that at no time during the prosecution of the instant case, or any of its parent cases have the claims been rejected on the state of the commercial market at the time of the invention. Instead they have been rejected on the combination involving Gough et al ('143) and **all** the teachings therein, irrespective of whether or not the assignee of the Gough et al ('143) patent has chosen to make a device manifesting those particular teachings available via a commercial venue. Regarding Declarant's assertions contained in paragraph 14, the examiner respectfully notes that, as set forth above with respect to paragraph 13, the absence of instructions in product literature does not remove from the U. S. Patent which is actually being applied to the claims, the teachings that are clearly contained therein. For example, as was already specifically set forth in the Final Rejection mailed June 24, 2009:

“Firstly, Gough et al ('143) teach that the number of antennas can be more than six; the antennas can be deployed from the distal end of the trocar, while others, from along its longitudinal axis; and that the device can be operated in a bipolar fashion, see column 3, lines 20-25:

“The number of deployed antennas can be four, five, six or more. Some of the antennas can be deployed out of the distal end of the trocar, while other antennas may be deployed from ports formed in the trocar along its longitudinal axis. The antennas may be RF electrodes operating in a monopolar mode, bipolar mode, or switchable between the two.””

The applied reference undeniably teaches bipolar application of power to the electrodes. Further the teachings of Gough et al ('143) that a group of six or more antennae may be disposed in the trocar and they may be situated such that “[S]ome of the antennas may be deployed from the distal end of the trocar, while other antennas may be deployed from ports formed in the trocar

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along its longitudinal axis.” The examiner notes that Figures 6A and 6B illustrate electrodes “deployed from ports formed in the trocar along its longitudinal axis” as recited in the specification of Gough et al (’143). The fact that one product from one company does not discuss this in the literature accompanying such product; the assertion of the lack of knowledge of any product available allowing bipolar or even absolute; and definitive proof of the complete absence of any product of this type available commercially fails to remove from the reference that is actually being applied to the claims the clear and unequivocal teachings set forth within the four corners of the reference, such as those teachings in the above quote. Further with reference to the electrode set as discussed with regard to paragraph 11, above, it is respectfully noted that using the broadest reasonable interpretation of the term “electrode set” the examiner could define all the electrodes coupled to one pole of the bipolar power supply as one set, with the electrodes coupled to the other pole of the power supply as the second set. Regarding Declarant’s assertions contained in paragraph 15, the examiner respectfully notes that Declarant’s interpretation of the disclosure at column 7, lines 21-30 of Gough et al (’143) notwithstanding, the above quoted passage from column 3 still fairly teaches this concept, as explained with regard to paragraphs 13 and 14, above, particularly with regard to the definition of the term “electrode set”. Regarding Declarant’s assertions contained in paragraph 16, the examiner respectfully notes that Declarant’s interpretation of the disclosure in Figures 7 and 8, and at column 7, lines 21-34 and the remainder of Gough et al (’143) notwithstanding, the above quoted passage from column 3 still fairly teaches this concept, as explained with regard to paragraphs 13 and 14, above, particularly with regard to the definition of the term “electrode set”. The examiner has no comment regarding the contents of paragraph 17. Regarding

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Declarant's assertions contained in paragraph 18, the examiner respectfully notes that there is no requirement that the construction of a *prima facie* case of obviousness that the feature in question be illustrated, merely that it be taught. While it may not be possible to produce the illustrated heating zone if the trocar illustrated in Figure 4 were insulated along its entire length (the examiner maintains otherwise, however, this is ancillary to the issue at hand) so too would it be impossible to produce the ablation volume explicitly described in column 8, lines 1-4, if the trocar of Figure 4 were not insulated to the tip, a fact which would have easily been recognized by one of ordinary skill in the art in the year 2000, since if it were not insulated, current would flow from the antennae to the trocar, thereby ablating the central core. And since one of ordinary skill in the art would read the Gough et al. ('143) for all of its teachings, one of ordinary skill in the art would realize that the insulating of the tip was provided by some structure, for example, the structure disclosed in column 5, lines 47-51: "[A]n insulation sleeve may be positioned around an exterior of trocar 14 and/or antennas 16. All or some of insulation sleeves 18 may be adjustably positioned so that a length of antenna electromagnetic energy delivery surface can be varied." Clearly if there is an adjustable sleeve on the trocar, it can be adjusted to cover the distal end, so as to allow the configuration in Figure 4 to be modified so as to be able to produce the ablation volume described in association therewith. With regard to the second point reproduced in paragraph 17, Declarant asserts that Figure 5, mentioned in the reproduced text, "does not suggest that two electrode sets each having a tubular member inner portion and an insulated outer portion and where the first support shaft is disposed within the second support shaft to provide a concentric tube configuration, as described in claim 28" since the discussion reproduced by Declarant was only directed to the length of insulation on the trocar, the lack of

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teaching other structures that were not directly related to the length of the insulation on the trocar is hardly surprising and does not serve to illustrate any deficiency in the examiner's line of reasoning. Regarding Declarant's assertions contained in paragraph 19, the examiner respectfully notes that in the examiner's view, the various teachings of Gough et al ('143) set forth above and in all the previous office actions, coupled with the level of skill of one of ordinary skill in the art, as set forth in the non-final rejection mailed December 23, 2008, and reproduced in the final rejection mailed June 24, 2009 and reproduced again here for applicant's convenience:

“the teachings of Gough et al ('143) must be evaluated for all its teachings one of ordinary skill in the art, and not merely the preferred embodiments (see *In re Boe* 149 USPQ 507). One of ordinary skill in the art is a surgeon familiar with radiofrequency ablation of tumors, and as such, the training for one of ordinary skill in the art would require not only 12 years of primary and secondary school, but 4 years of college, 4 more years of medical school, and additional years as an intern before qualifying as a surgeon qualified to ablate tumors with radiofrequency energy. Of necessity, then one of ordinary skill in the art would also be familiar with basic electrical principles, such as the relationship of current and power, the appropriate connections required to cause electrical energy to be applied at the desired locations, and the ability of insulators to block the flow of electrical energy.”

This level of skill is very high, thus the concept of using two devices as taught by Gough et al ('143), rather than moving one around, which would take significantly more time, time during which the operating theater is not able to be used for other surgeries and during which the patient is under anesthesia, both of which are undesirable, since this makes waiting times for surgeries longer and it is desirable to minimize the time the patient is under anesthesia, since this can avoid deleterious reaction, official notice of all of which is hereby taken. Thus one of ordinary skill in the art, faced with the desirability of reducing operating room time and time under anesthesia for the patient, would easily determine that the use of two such devices as

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taught by Gough et al ('143) simultaneously would produce the same ablation patterns as those which Gough et al ('143) discusses producing by moving around a single device, in less time. Further, having made this determination, employing devices with a coaxial or side by side configuration to effect this time savings would also be easily within the grasp of one having such a high level of skill, the coaxial arrangement, because this would enable the relative positions of the ends of the electrode outputs to be known with high precision, and the side by side configuration, because this would allow the treatment of tumors the axes of which are skewed with respect to the axes along which the devices are able to be inserted or which are irregularly shaped.

Turning now to applicant's arguments, with regard to the disclosure relating to Figures 7 and 8 of Gough et al ('143), applicant asserts that "Gough et al. '143 only shows a vertical plane of energization provided by two electrodes in each electrode set being in the plane of the paper on which Fig. 8 is presented" this is not convincing, however, as Gough et al. ('143) clearly discuss the use of 6 or more electrodes in the device, employing this number of electrodes would clearly "define a plane" as required by the claim. Applicant is respectfully reminded that the teachings of Gough et al. ('143) are not limited to the Figures therein, but include the written disclosure and the claims as well.

With regard to the discussion of the bipolar energization of the electrodes as discussed on page 6, as this portion of the office action was directed towards the teaching of providing insulation on the tip of the trocar and to show the possession and conveyance by Gough et al. ('143) to one of ordinary skill in the art, the knowledge that using a bipolar mode to allow current to flow from one electrode to the other along the axis of the device was known and

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desirable. In view of the latter teaching to provide multiple electrodes for multiplied effect (and to save time, as set forth above) would have been obvious (see *St. Regis Paper Co. v. Bemis Co., Inc.*, 193 USPQ 8, 11). With regard to the two shafts having a particular construction that is in a coaxial or side by side configuration, applicant argues that “this modification was not taught by the real world contemporaneous embodiments” and refers to the Haemmerich Declaration. The examiner must respectfully note that, as set forth in the response to this argument in the Haemmerich Declaration (and applicant is referred back to the response to these paragraphs in the Haemmerich Declaration for a more complete treatment of this matter), the claims are not rejected under the “real world contemporaneous embodiments” discussed by Declarant, but under the Gough et al (’143) reference, and in view of the teachings of this reference and the knowledge of one of ordinary skill in the art at the time of the invention, such a modification would have been obvious at the time of the invention, for the reasons set forth above.

Continuing, applicant argues that the examiner’s proposed modification of the Gough et al (’143) reference would be a modification of energizing one probe to energizing two. The examiner maintains the determination of obviousness, based on the time savings of using two probes simultaneously, rather than relocating a single probe, as set forth above, and in view of the obviousness of the provision of multiple parts for multiplied effect, as also set forth above. With regard to the issue of the electrodes being at predetermined spacings, applicant’s arguments are somewhat confusing, in that applicant argues “that there is no teaching in Gough et al. ‘143 of kits with spacings for different sizes of tumors or presetting the spacing before handling of the device by a physician” (see the instant response, page 9, fourth full paragraph). This appears to be asserting that the provision of predetermined distances between the electrodes was unknown.

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However, looking at the reference to Gough et al ('143), clearly the embodiment where the more proximal electrodes are extended through apertures in the shaft have a predetermined "spacing before handing of the device by the physician" unless applicant has found a passage in Gough et al ('143) that has eluded the examiner and directs the physician to machine these apertures in the device him- or herself in the operating room. Regardless of this, however, any limitation relating to who does the presetting is entirely absent from all the claims, and would likely be non-limiting in the case of the apparatus claims. Next applicant admonishes the examiner for his reliance on the level of one of ordinary skill in the art, noting that mere conclusory statements alone cannot sustain obviousness. The examiner respectfully notes that each statement relying on the knowledge and/or level of skill of one of ordinary skill in the art has been provided with a rationale supporting the conclusion, thus applicant's argument in this regard is not well founded.

The examiner will now address the features which applicant believes are not present in and/or are not obvious modifications of Gough et al ('143).

As to the limitation of two sets of three electrodes defining two respective axially spaced apart planes, it is the examiner's view that it would be obvious to modify e.g. the embodiment shown in Figures 5 or 8 to include 3 electrodes, due to both the obviousness of providing duplicate parts for multiplied effect (as determined in *St. Regis v. Bemis*, cited above) and the explicit teaching of providing more than 2 (i.e. 3, 4, 5, 6, or more) electrodes, as set forth in column 3, lines 20-25 of Gough et al ('143), discussed above. Further, one of ordinary skill in the art would be motivated to provide these electrodes equally spaced around the circumference of the shaft, since this would provide uniform treatment. Thus this limitation is clearly taught by

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Gough et al ('143), and obvious under Gough et al ('143) in view of the knowledge of one of ordinary skill in the art.

As to the connection of the bipolar power supply between the two sets of three electrodes, it is the examiner's view that the broad statement in Gough et al ('143) that: "The number of deployed antennas can be four, five, six or more. Some of the antennas can be deployed out of the distal end of the trocar, while other antennas may be deployed from ports formed in the trocar along its longitudinal axis. The antennas may be RF electrodes operating in a monopolar mode, bipolar mode, or switchable between the two." (see column 3, lines 20-25), is sufficient to teach this. However, it is additionally noted that with regard to the embodiment of Figure 5 is specifically discussed as being able to "be operated in the bipolar mode between the two antennas" (see Gough et al ('143), column 8, lines 9-10). And in view of applicant's acknowledgement "that Fig. 8 of Gough et al. '143 only shows a vertical plane of energization provided by two electrodes in each electrode set being in the plane of the paper on which Fig. 8 is presented" (see the instant response, the first sentence of the paragraph bridging pages 7 and 8), these teachings coupled with the provision of more antennae, as discussed with regard to the previous perceived deficiency of Gough et al ('143), clearly teaches and/or renders obvious this limitation as well.

With regards to the limitation of "insulation of a support shaft between two electrode sets", as set forth above, it is the examiner's view that the provision of an additional device of any of the types taught by Gough et al ('143) in e.g. a side by side (or other) configuration would have been obvious to the artisan of ordinary skill in the art, given the obviousness of providing duplicate parts for multiplied effect, as set forth above, and additionally, as already set forth, one

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of ordinary skill in the art is a surgeon familiar with radiofrequency ablation of tumors, and as such, the training for one of ordinary skill in the art would require not only 12 years of primary and secondary school, but 4 years of college, 4 more years of medical school, and additional years as an intern before qualifying as a surgeon qualified to ablate tumors with radiofrequency energy. Therefore, of necessity one of ordinary skill in the art would also be familiar with basic electrical principles, such as the relationship of current and power, the tendency for current to flow along many available paths, the appropriate connections required to cause electrical energy to be applied at the desired locations, the ability of insulators to block the flow of electrical energy, and the desirability of having the flow of energy blocked in certain locations and situations. Having established the level of skill of one of ordinary skill in the art, the information one of ordinary skill in the art would glean from the teachings of Gough et al ('143) will be determined. The establishment of the teaching and/or obviousness of providing at least three electrodes in each "set" and bipolar energization of the two sets with respect to one another have already been established above. Gough et al ('143) also teach that the electromagnetic delivery surface may be varied by varying the amount of the trocar and or antennas that are covered by the insulative sleeve, and that the insulative sleeve can contain apertures that permit the passage of antennae through the insulative sleeve while it is in place on the trocar, see column 5, lines 48-55:

"An insulation sleeve 18 may be positioned around an exterior of trocar 14 and/or antennas 16. All or some of insulation sleeves 18 may be adjustably positioned so that the length of an antenna electromagnetic energy delivery surface can be varied. Each insulation sleeve 18 surrounding a trocar 14 can include one or more apertures. This permits the introduction of a antenna 16 through trocar 14 and insulation sleeve 18."

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Gough et al ('143) also teach that when multiple antennae are used, they can produce “a substantially complete ablation volume formed between antennas 16 with a minimal core that is not ablated” (see Figure 4, and column 8, lines 2-4), as one of ordinary skill in the art would readily appreciate, the only way a non-ablated core can be produced is if there is no current flowing between the antennae and the trocar, if there were current flow, there would be commensurate ablation of tissue at the central core and this teaching would cause one of ordinary skill in the art to conclude that the trocar is insulated to produce this effect. Still further, Gough et al ('143) also teach that when multiple antennae are used, the antennae may be situated at different axial positions along the trocar and “can be operated in a bipolar mode between the two antennas 16, or between a antenna 16 and trocar 14” (see Figure 5, and column 5, lines 9-11). It will be readily apparent to one of ordinary skill in the art that if either or both of the antennae of the device of Figure 5 are energized as part of the bipolar energization thereof, when such energization is intended to be between the two antennae, current would also flow to the uninsulated trocar, the fact that Gough et al ('143) explicitly specify that that the bipolar mode can be between the antennae or the trocar would clearly indicate to one of ordinary skill in the art that that in the instance where the bipolar mode is between the antennae, the trocar must be insulated, else it, too would sink the current coming from the antennae. At this point the examiner must respectfully note that applicant has made much of the fact that Gough et al ('143) does not expressly show insulation on the ends of the trocars, however, as the disclosure of Gough et al ('143) is written with the knowledge of one of ordinary skill in the art in mind, it is the examiner's view that the lack of showing of insulation in some cases is done for simplicity, with the understanding that one of ordinary skill in the art will readily recognize where insulation

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is necessary. As an example of this, the illustrations of the probes of Figures 4 and 5 show no insulation whatsoever. However, even assuming *arguendo* that one of ordinary skill in the art would not understand that the proximal portion of the device should be insulated, the moment the surgeon actuated the radiofrequency energy, and received a jolt from the uninsulated proximal portion of the shaft, the need for such insulation would become immediately apparent, even if the level of ordinary skill were such that one of ordinary skill in the art would not understand immediately that it should be done without being shocked. Similarly, when the exterior tissue of the patient began to smoke and ablate at the point where the proximal end of the device exited the patient, this would indicate to one of ordinary skill in the art that insulation at this point was in order. Essentially, the provision of insulation on metallic portions of the device which are expressly recited as not being desirable for receiving electrical current (e.g. the trocar of Figure 5 when the antennae alone are operated in bipolar mode) would have been obvious to one of ordinary skill in the art.

Concerning the limitation related to coaxial shafts, where each shaft is tubular metal with an insulated outer surface, applicant asserts this is not shown or suggested by Gough et al ('143). The examiner notes that the only passage located in the originally filed disclosure that discusses the composition of the coaxial shafts was: "Shaft 18c and 42 are typically metallic and thus are coated with insulating coatings 45 and 46, respectively, to ensure that any current flow is between the exposed wires 32 rather than the shafts 18c and 42" (see the originally filed disclosure, page 10, first full paragraph, last sentence). Clearly the requirement for metallic shafts is not critical, but merely a matter of convention ("are typically metallic"). As already set forth in the art rejection, but repeated here for applicant's convenience: "it would have been

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obvious...to provide each shaft as a insulated metallic tubular member in a coaxial configuration, since this is not critical; is well within the skill of one having ordinary skill in the art; provides no unexpected result; and would make the device more sturdy” wherein the term “sturdy” is intended to encompass not only wearability, but also having the appropriate stiffness for the application.

Concerning the side-by-side shafts, this has been addressed above with respect to the provision of duplicate parts for multiplied effect and to save time.

Concerning the predetermined axial offset, this has been discussed with respect to the provision of cut outs in the trocar to allow antennae to be deployed at given (predetermined) distances from the antennae which are deployed from the end of the device. It can also be provided by employing a group of separate antennae which are of differing lengths, which would be obvious, since it would be unrealistic for one of ordinary skill in the art to expect all tumors to begin at a uniform depth beneath the skin and to have a uniform size or extent below the body surface.

Therefore, as can readily be seen from the foregoing, the examiner’s assertions concerning both the teachings of Gough et al (’143) and that which would have been obvious to one of ordinary skill in the art, in view of the teachings contained in Gough et al (’143) are correct, therefore applicant’s assertions and arguments based on the erroneous presumption that the teachings attributed to Gough et al (’143) and the obvious conclusions that one of ordinary skill in the art would draw therefrom, are not present therein, are not well founded.

With regard to what applicant refers to as “Factual issue No. 1”, while Figure 8 can be made to read on the claims as set forth above, so can Figure 5 and any of the other embodiments

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when used in conjunction with another device of the same kind to save time, and which regardless of any time savings is obvious, as held in *St. Regis v. Bemis*, as set forth above.

Concerning the limitations of claims 7, 8, and 22, also as set forth above, the provision of evenly distributed electrodes would have been obvious to the artisan of ordinary skill, since this would provide a uniform distribution of ablative energy. Thus applicant's conclusion is flawed

With regard to what applicant refers to as "Factual issue No. 2", applicant plucks another patent by Gough et al at random, which is neither in the chain of copendency of the reference which is actually applied to the claims, nor incorporated therein, in the hopes of obscuring the fact that Gough et al ('143) clearly and explicitly teach that the bipolar transfer of energy can occur either between the two antennae or between the antennae and the trocar, as set forth above. However, the absence of a teaching in an unrelated reference, which has never been applied to the claims, cannot remove from the reference actually applied to the claims, the teaching which is explicitly recited therein. The reference to the Haemmerich Declaration, which instead of referring to a patent that has not been applied to the claims, refers to commercial products which have not been applied to the claims, is similarly unpersuasive, as set forth above.

With regard to what applicant refers to as "Factual issue No. 3", applicant "sincerely urges" that there is no evidence to support the notion that the trocar is insulated other than by sleeve 18. The examiner again refers to the passage at column 8, referring to Figure 4 and the knowledge of one of ordinary skill in the art, as set forth extensively above, and which will not be repeated here, for brevity. If applicant wishes to persuade the examiner that there is no teaching of insulation on the trocar in Figure 4 in Gough et al ('143), all applicant need do is explain exactly how the heating pattern expressly described at the top of column 8 therein would

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be produced in the absence of insulation on the trocar. Absent this, applicant's arguments are not convincing.

With regard to what applicant refers to as "Factual issue No. 4", the examiner acknowledges that the provision of two shafts, each composed of a metallic inner portion and an insulated outer portion is not taught by Gough et al ('143). However, the examiner also notes that this limitation is not critical and configuring the device of Gough et al ('143) as such would have been obvious to the artisan of ordinary skill, either by providing duplicate parts (i.e. duplicate multiple antenna devices) or by altering the composition of the two sheaths in Figures 7 or 8 to include both metal tubes (for strength, support, and rigidity) and insulators (to block the current from flowing from the antennae into the support shaft via the tissue or any fluid infused, as disclosed with respect to Figure 6(c)). Applicant's assertion that the issue of criticality "is not seen to relate to combination claims in the electrical-mechanical arts unless a range or dimension is at issue" is noted, however, this assertion is erroneous. Applicant is referred to MPEP §716.02 - §716.02(g) and §2164.08(c), for example. A prima facie case of obviousness having been established by the examiner, by virtue of the rebuttal of the assertions and arguments submitted in the Haemmerich Declaration and applicant's remarks, the discussion of a lack of showing of unexpected results is appropriate. Thus this argument is not convincing.

With regard to what applicant refers to as "Factual issue No. 5", the examiner acknowledges that the provision of two shafts in a side-by-side configuration is not explicitly taught by Gough et al ('143), however, as set forth above it is an obvious variation of the Gough et al ('143) device and method, as it would save time over the use of a single device that was then moved around, and merely constitutes the provision of duplicate parts for multiplied effect

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as set forth in *St. Regis v. Bemis*. As with respect to “Factual issue No. 4”, above, the discussion of the criticality and lack of unexpected results deriving from the limitation are proper and appropriate. Thus this argument is not convincing.

With regard to what applicant refers to as “Factual issue No. 6”, applicant argues that the examiner misunderstands the claim limitation. The examiner believes he does understand the claim limitation. It is simply that when inserting two devices such as the devices taught by Gough et al ('143) (duplication of parts for multiplied effect and/or to save time in the operating room and/or to minimize the time the patient is under anesthesia), this is what would be required to produce a non-predetermined spacing. Applicant has yet to explain in what way the trocars with apertures machined into them in addition to the terminal end of the trocar to provide for antenna placement does not constitute a “predetermined spacing”. For example, the embodiment show in Figure 5 of Gough et al ('143) is manipulated, i.e. rotated, but the spacing of the electrodes is undeniably “predetermined”. Thus applicant’s arguments are not convincing.

The amendment filed December 18, 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: “the first and second electrode set each comprising 3 wires positionable at angularly offset radial points around the shaft configuration”.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure is silent on “the first and second electrode set each comprising 3 wires positionable at angularly offset radial points around the shaft configuration”.

Claims 1-9, 13, 16-22, and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al ('143) in combination with Swanson et al. Gough et al ('143) teach a device as claimed except for the specific disclosure that the current is passed from one electrode set to the other and the specific frequencies claimed. Swanson et al teach using frequencies in the 1 KHz range, to which tissue has a high resistivity. It would have been obvious to the artisan or ordinary skill to employ the frequencies in the 1 KHz range, since these are frequencies to which tissue has a high resistivity, as taught by Swanson et al, and would thus produce more heating, and to configure the device to produce current flow in the axial direction when there are multiple electrodes, since this would ablate the tumor more quickly than the procedure involving rotation, discussed by Gough et al ('143), and to provide multiple sets of electrodes with at least three electrodes, since this is not critical; is well within the skill of one

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having ordinary skill in the art; provides no unexpected result; and is merely the provision of multiplied parts for multiplied effect, to provide each shaft as a insulated metallic tubular member in a coaxial configuration, since this is not critical; is well within the skill of one having ordinary skill in the art; provides no unexpected result; and would make the device more sturdy, to provide the two sets of electrodes at a fixed predetermined distance, for example by providing trocars of different fixed lengths to be used together, since this would assure that the preset distance was not altered on insertion of the device or during the procedure, and to provide the insulating sleeve along at least the length of the trocar between the two sets of antenna, since this would prevent current from being grounded through the trocar, and to employ the trocars in a side by side configuration, rather than coaxial, since this is not critical; is well within the skill of one having ordinary skill in the art; provides no unexpected result; and would enable independent placement of the trocars, thus producing a device and method such as claimed.

Applicant's arguments filed December 18, 2009 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30 p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3769